REMARKS

Applicants respectfully request that the foregoing amendments be made prior to examination of the present application.

Claim Rejections Under 35 USC 102

Claims 1-2 are rejected as being anticipated under 35 USC 102(b) by Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert"). For the following reasons, applicants request that this rejection for anticipation be withdrawn.

35 USC 102(b), is reproduced below.

> A person shall be entitled to a patent unless - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Claim 1, the independent claim under examination, recites that the claimed compound is administered to a subject. Ebert does not disclose administration to a subject but rather *in vitro* assays of a rat cortical wedge preparation and a neonatal rat spinal cord preparation. See abstract and Sections 2.2 and 2.3. *In vitro* assays are not the same as administration to a patient and therefore the assays *per se* cannot anticipate the present invention.

As the Examiner has observed, there is a single mention in Ebert of the phrase "clinical studies" in the very last sentence, which reads "[c]linical studies are now under way to investigate whether orally administered (*S*)-norketamine may have fewer side effects than (*S*)-ketamine." For the following reasons, applicants contend that this sentence does not anticipate the present invention.

This a hearsay statement alleging clinical studies, but nothing is discernable from this statement. Ebert does provide any data or information related to actual administration of (*S*)-norketamine. Therefore, whether the alleged clinical trials even actually took place, is unknown. Moreover, there are many steps that take place in the process of prosecuting a clinical study before administration of a drug takes place. For example, a clinical study must

be documented, funded, and approved by an internal review board before patients can be approached. Patients must also be selected and give their informed consent. All this occurs before any drugs can be administrated. Ebert makes no mention of how far the alleged clinical studies have progressed, assuming, they were actually occurring.

The Examiner is also reminded that under 35 USC 102(b), a public use outside of the United States is not considered prior art. All of the authors of Ebert are stated to be associated with either The Royal Danish School of Pharmacy, Copenhagen, Demark or the University of Copenhagen, Copenhagen, Demark. The Ebert article itself was published in the European Journal of Pharmacology. Therefore, it is logical to conclude that if any administration of (*S*)-norketamine did actually occur, it was outside of the United State, which under 35 USC 102(b), is not prior art.

Applicants are also filing a 132 Declaration of Dr. Mark S. Kleven, a Ph D pharmacologist. Based on the fact that Ebert was published 10 years ago, and there is no publication to-date relating to clinical studies of (*S*)-norketamine, Dr. Kleven concludes that "it is most certain that either (*S*)-norketamine was never tested in clinical trials, or if such clinical trials did occur, they were unsuccessful, discontinued and never publicized."

In conclusion, for the above reasons, applicants contend that Ebert does not anticipate the present invention and therefore the rejection under 35 USC 102(b) should be withdrawn.

Claim Rejections Under 35 USC 103

Claims 5-9, 12-18, 21-25, 28-31 and 71 are rejected under 35 USC 103(a) for obviousness over Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert") in view of US Patent Application 2005/0148673 ("Harburt").

As discussed above Ebert does not disclose actual oral administration. Moreover, given the decade long time lapse between the publication of Ebert and the present time, with no followed information regarding the alleged clinical studies of Ebert, a skilled artisan would conclude Ebert to be a failure by others and that there existed a long-felt need in the

art. Dr. Kleven, in the attached 132 Declaration states "it is most certain that . . . if such clinical trials did occur, they were unsuccessful, discontinued and never publicized."

Section 716.01 of the MPEP states that "evidence traversing rejections, when timely presented, [i.e. before a final office action] must be considered by the examiner whenever present." Therefore, the expert testimony of Dr. Kleven must be considered by the examiner.

The Federal Circuit has held that testimony of an expert related to firsthand knowledge of unsolved needs in the prior art is evidence of the state of the art. *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 789. Failure by others to satisfy a long-felt need is evidence of nonobviousness. *Dow Chemical Co. v. American Cyanamid Co.*, 816 F.2d 617, 623, 2 USPQ.2d 1350, 1355; *In re Piasecki*, 745 F.2d at 1475, 223 USPQ at 790.

Hubert does not relate to the administration of norketamine, but rather only discloses various formulations of ketamine, and therefore, does not cure the deficiencies of Ebert.

Applicants have evidenced the failure of others, and in light of the long lapse between the 1997 publication date of Ebert and the 2002 priority date of the present application, there existed a long-felt need in the art. Therefore, the present invention is not obvious and the outstanding rejection for obviousness should be withdrawn.

Conclusion

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: October 9, 2007

By: _____

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